Ref: Syn/CS/SE/IP/2022-23/Jan/08

Syngene International Limited
Biocon SEZ, Biocon Park, Plot No. 2 & 3,
Bommasandra Industrial Area, IV Phase,
Jigani Link Road, Bengaluru 560099,
Karnataka, India.
T +91 80 6891 8000
F +91 80 6891 8808
CIN: L85110KA1993PLC014937
www.syngeneintl.com

January 23, 2023

To, The Manager, BSE Limited Corporate Relationship Department Dalal Street, Mumbai – 400 001	To, The Manager, National Stock Exchange of India Limited Corporate Communication Department Bandra (EAST), Mumbai – 400 051
Scrip Code: 539268	**Scrip Symbol: SYNGENE**

Dear Sir/Madam,

Sub: Investor Presentation under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

With reference to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, please find enclosed the Investor Presentation for the quarter ended December 31, 2022. The Company will use this presentation for any meeting scheduled with analysts or institutional investors up to March 31, 2023.

The above-mentioned Investor Presentation will also be available on website of the Company www.syngeneintl.com.

This is for your information and records.

Thanking You,

Yours faithfully,
For **SYNGENE INTERNATIONAL LIMITED**

PRIYADARSHINI MAHAPATRA

Digitally signed by PRIYADARSHINI MAHAPATRA
DN: c=IN, o=Personal, pseudonym=bc2eb3d598e4b4695dfab584d8c4954317f2c9b276b0ead69f4bb6de415c5150d, 2.5.4.20=3b3032863a60d6cf503dc962d0b81de07d5cef26229a00b5f723a1ef57ab0005, postalCode=751015, st=ODISHA, serialNumber=df67e39aa5435d22f718c22d0516d97afb1208536f4f1860285e06c72d0c9992, cn=PRIYADARSHINI MAHAPATRA
Date: 2023.01.23 21:05:52 +05'30'

Priyadarshini Mahapatra
Company Secretary and Compliance Officer

Enclosed: Investor Presentation.

Syngene

Putting Science to Work

Investor Presentation

December 2022

Safe harbour

Certain statements in this release concerning our future growth prospects are forward-looking statements, which are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those contemplated in such forward-looking statements.

Important factors that could cause actual results to differ materially from our expectations include, amongst others general economic and business conditions in India, business outlook of our clientele and their research and development efforts our ability to successfully implement our strategy, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currencies, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition, changes in political conditions in India and changes in the foreign exchange control regulations in India.

Neither the company, nor its directors and any of the affiliates have any obligation to update or otherwise revise any statements reflecting circumstances arising after this date or to reflect the occurrence of underlying events, even if the underlying assumptions do not come to fruition.

Contents

1 Operating Highlights

Syngene

Q3 FY23 performance

Operating Highlights

- Positive performances in all divisions
- Sustained growth in Research divisions - Discovery Services and the Dedicated Centers
- Development Services growth was primarily driven by repeat orders from existing clients and a growing number of collaborations with emerging biopharma companies
- The Company completed the construction of a state-of-the-art, sterile fill-finish facility which successfully cleared an inspection by the Central Drugs Standard Control Organization (CDSCO), making it compliant for GMP production from the fourth quarter onwards. With the commissioning of this facility, the Company will offer end-to-end solutions in drug product development and manufacturing for clinical supplies of small and large molecule injectables
- In Manufacturing Services, the Company successfully completed the US Food and Drug Administration (US FDA), European Medicines Agency (EMA) and Medicines and Healthcare products Regulatory Agency (MHRA) regulatory audits for its biologics manufacturing facility
- With the Good Manufacturing Practice (cGMP) certifications from the regulatory agencies in place, the Company is on track to execute manufacturing of drug substance at a commercial scale and progress its Biologics manufacturing services growth strategy
- Continued to invest in new infrastructure, technology, capability-building and talent development

Q3 Financial Highlights

Total Revenue **Rs. 8,031 Mn**	Reported EBITDA **Rs. 2,482 Mn**
Profit After Tax **Rs. 1,097 Mn**	EBITDA **Margin at 30.9%** PAT **Margin at 13.7%**

Upgraded FY23 full year guidance maintained

Parameter	FY23 Guidance (April 2022)	Revised FY23 Guidance (July 2022)	FY23 Guidance (December 22)
Revenue from operations	Mid-teen growth	High- teen growth ↑	High- teen growth ↔
EBITDA Margin	EBITDA margin around 30%	EBITDA margin around 30% ↔	EBITDA margin around 30% ↔
PAT* Growth	PAT growth expected to be in single digit	PAT growth expected to be in single digit ↔	PAT growth expected to be in single digit ↔

*before exceptional items

2 Syngene – Putting Science to Work

Syngene

Partner in innovation: #Puttingsciencetowork

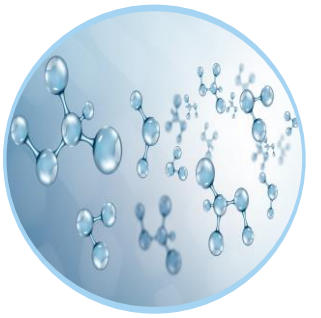
Who we are and what we do

We aim to be a world class partner delivering innovative scientific solutions for clients

We offer integrated solutions across research, development and manufacturing

Sector expertise include pharmaceuticals, biotech, nutrition, animal health, consumer goods and specialty chemicals

Our team includes more than ~5,000 scientists out of total ~6,000 headcount, operating across 3 state-of-the-art campuses located in India's leading life science hubs: Bangalore, Mangalore and Hyderabad.



Established track record in discovery research and development for small and large molecules. Emerging presence in commercial manufacturing.

Key facts and figures

400+
active clients

15
collaborations
with top 20 pharmaceutical companies

400+
patents
held with clients

World class infrastructure
of 2 Mn sq. ft. qualified to meet international standards

Rs. 39,435 Mn
(US$526Mn*)
Gross Block of Investments ^

Rs. 26,570 Mn
(US$354Mn*)
FY22 Revenue

Rs. 4,211 Mn
(US$56Mn*)
FY22 PAT before exceptional item

~6,000 headcount
including ~5,000+
talented scientists

*All figures are as on March 31, 2022, unless otherwise specified. *At Rs75/US$ ^Tangible and Intangible Assets*

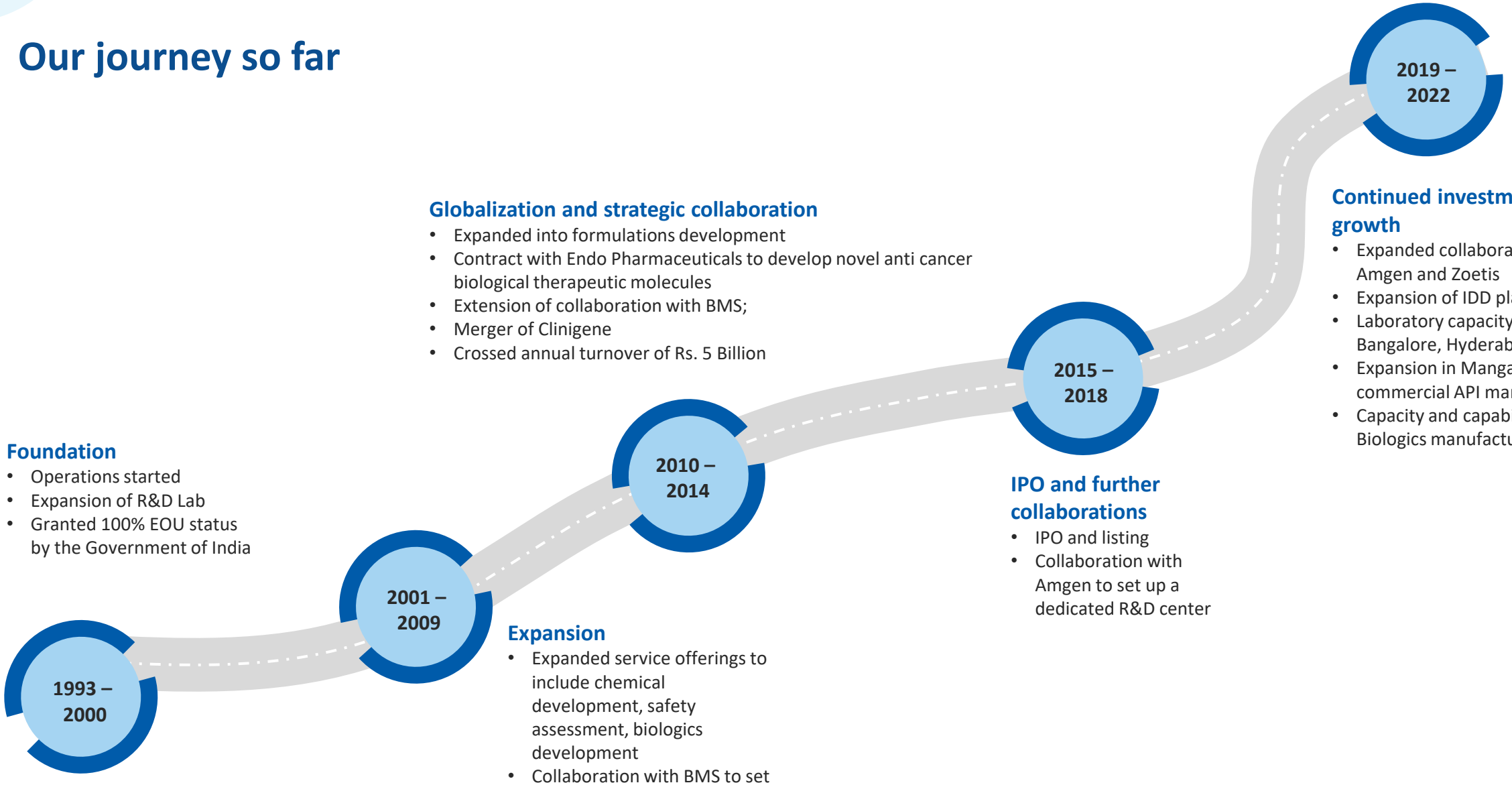
International accreditations

- USFDA,OHSAS 18001
- GLP, cGMP, AAALAC & CPCSEA Certified facilities
- CAP accreditation, ISO/IEC 27001:2013 accreditation
- EMA and PMDA approved, AAALAC accredited facility
- The safety assessment laboratories and large molecule bioanalytical lab are ISO IEC 17025:2017 certified by the National Accreditation Board for Testing and Calibration Laboratories (NABL)

Our experience spans multiple industry segments and partnerships with global leaders across the world

Large & mid-sized biopharma	Emerging biopharma	Universities	Animal health	Agrochem	Consumer products
Bristol Myers Squibb	Genmab	Weill Cornell Medicine	zoetis	FMC	Unilever
Albireo	SOSEI HEPTARES	Indiana University	MERCK		
gsk	rodin THERAPEUTICS	UK Research and Innovation	BAYER		
SANOFI	PharmAust LIMITED	University of Glasgow			
Johnson & Johnson	ASCENEURON A Neurodegeneration Therapeutics Company	VCU Virginia Commonwealth University			
MERCK		King Abdulaziz University			
AMGEN					
abbvie					

Our journey so far



Foundation
- Operations started
- Expansion of R&D Lab
- Granted 100% EOU status by the Government of India

Expansion
- Expanded service offerings to include chemical development, safety assessment, biologics development
- Collaboration with BMS to set up BBRC, Syngene's first dedicated R&D Center

Globalization and strategic collaboration
- Expanded into formulations development
- Contract with Endo Pharmaceuticals to develop novel anti cancer biological therapeutic molecules
- Extension of collaboration with BMS;
- Merger of Clinigene
- Crossed annual turnover of Rs. 5 Billion

IPO and further collaborations
- IPO and listing
- Collaboration with Amgen to set up a dedicated R&D center

Continued investments and growth
- Expanded collaboration with BMS, Amgen and Zoetis
- Expansion of IDD platform
- Laboratory capacity expansion in Bangalore, Hyderabad
- Expansion in Mangalore for commercial API manufacturing
- Capacity and capability addition in Biologics manufacturing

Our broad capabilities, spanning the value chain, facilitates integration and captures additional benefits for clients

Research business

Discovery Services

Flexible Platform with capability across multiple modalities including small molecule, large molecule, peptides, oligonucleotides, antibody drug conjugates, PROTACs

SynVent - our proprietary platform for Integrated Drug Discovery

Dedicated R&D Centers

Ring-fenced infrastructure for exclusive operations for an individual client

Dedicated, multi-disciplinary team of scientists

Access to entire Syngene ecosystem for specialist research and development operations

Development and Manufacturing business

Development Services

Pre-clinical to clinical trials

Drug substance and drug product development

Associated services to demonstrate the safety, tolerability and efficacy of the selected drug candidate

cGMP-compliant manufacturing of clinical supplies, and registration batches for small molecules

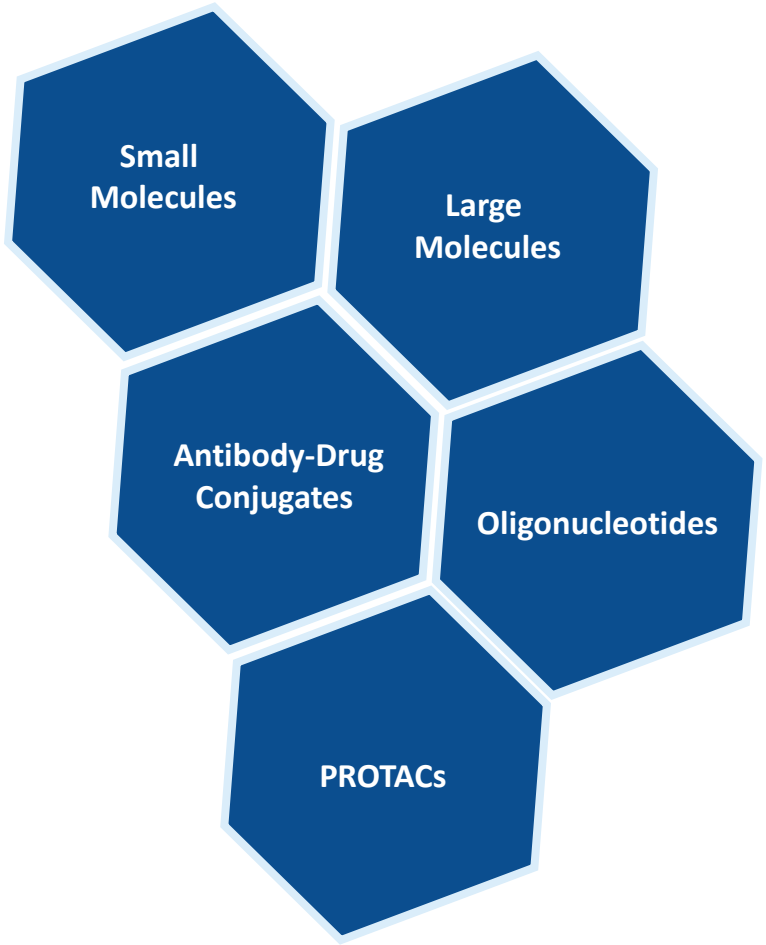
Manufacturing Services

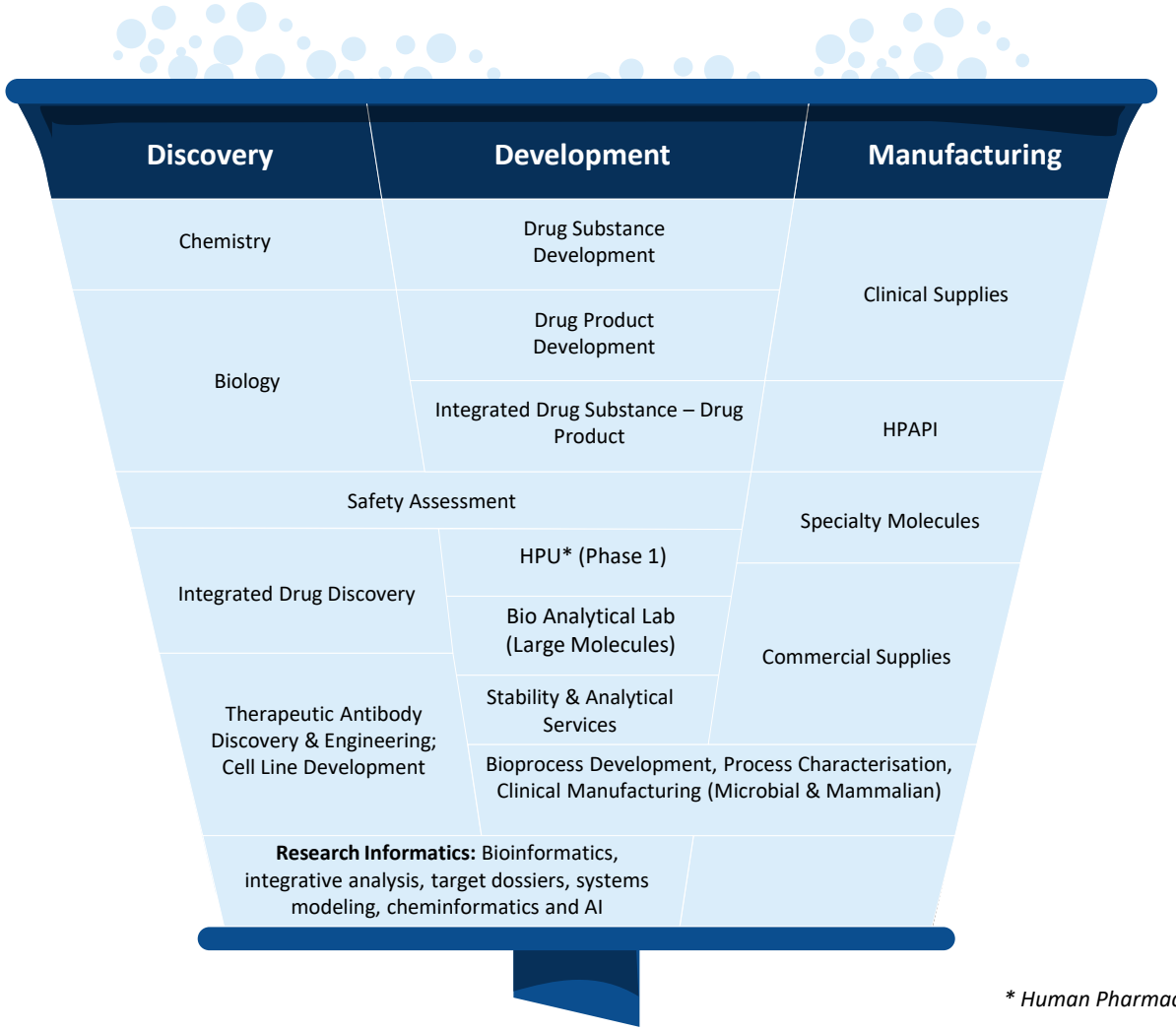
Manufacturing of small and large molecules for commercial supplies

cGMP-compliant facilities

State-of-the art API manufacturing and Biologics manufacturing facilities

A 'one-stop-shop' for discovery research, development and manufacturing services (small and large molecules)





** Human Pharmacology Unit*

Flexible collaboration models

1

Dedicated R&D centers

- Dedicated scientific and support teams work exclusively on the client's projects
- Clients are provided with customized and ringfenced infrastructure
- Long-term strategic alliances that last usually five years or more

2

Full time equivalent (FTE)

- Pre-defined numbers of scientific personnel from pre-determined disciplines work full-time on client projects
- Deliverables and team composition evolve as the project advances
- Agreements are typically renewed annually

3

Fee for service

- Client contracts for agreed services within a defined scope
- Flexible, 'on demand' personnel and research infrastructure deployed to achieve the project objectives
- Engagements may be short-term or long-term

4

Productivity-based model

- Resources and services are directly linked to productivity generated by our team

5

Risk-reward

- Relationship spans a portfolio of milestone-driven research projects
- Client benefits from reduced upfront payments in exchange for significant success-based milestone payments against pre-agreed criteria

6

Delivery-based contract for CDMO business

- Per kg or per batch model with built-in milestones progressing towards achievement of outcome and delivery of drug substance, drug product

… we are open to any single or combination of above

Our state-of-the-art infrastructure

Bangalore campus
90 acres housing most of Syngene's capabilities

Biologics
Bangalore campus
Manufacturing plant scale:
Mammalian- ~100-2000L
Microbial - ~200-500L

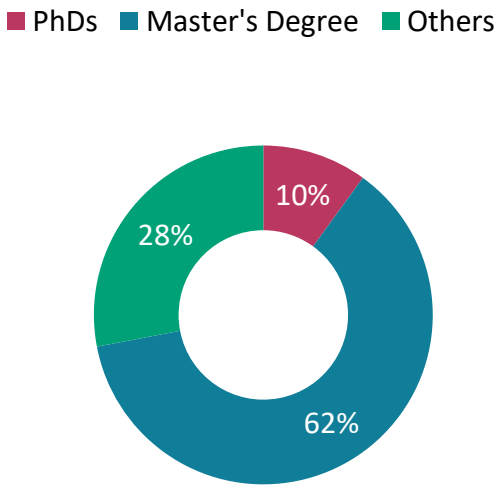
Discovery Services
Hyderabad campus
commenced operation in
Aug 2019

API Manufacturing
Mangalore campus
Commissioned March 2020
Capacity: 70KL
Reactor size: 2-12KL

Experienced workforce: building capabilities and careers

~6,000
total headcount

5000+ scientists delivering high quality solutions – create a competitive edge



Inspiring technical excellence and providing opportunities to grow

Nurturing young talent and enhancing science skills

- Syngene Training Academy offers new graduate recruits a six-month extended induction to help them understand the Company's vision and values while acquiring the skills to be an industrial scientist
- Science Certification Program is open to all employees to enhance their capabilities keep their skills up to date and provide opportunities for continuous learning.

Developing leaders and managers

- Emerging Leaders Development Program is designed to help strong managers transition from managerial to leadership roles
- Manager Development Program is designed for first- and second-line managers to develop basic management skills and performance management to help them manage their teams and ensure that they are making a positive contribution to the organizational goals.

Promoting workplace diversity

- The Company has strong equal opportunity policies to protect against all forms of discrimination and provide a workplace where all employees can deliver their best work
- Support provided to parents of young families. 27% of employees are female and 22% of management positions are held by females

Operational robustness driving strategy execution

Continuous improvement embedded in operations driven by certified operational leaders

Six Sigma Black Belt certified staff in each service line and support function
Green belt certified staff across operations
All employees white belt certified

Quality management system: digitized and audit-ready

70 customer and regulator audits in the last financial year
7 successful USFDA audits in the last 4 years

Client-focused commercial organization

Leaders based in the US, Europe, UK and Asia
Close to client locations

Focused execution through strong Project Management

Structured program management for executing client projects enabled by SynPro platform and SynPro Academy ensuring delivery of client projects

Digital as a differentiator

AI capability in all research teams
IoT for maintenance and infrastructure reliability
Data Management, IT infrastructure and security systems to strengthen our proposition as a strategic partner to clients

Strategic Sourcing that makes a difference

Strategic supplier management to avoid supply chain disruption
Supply distributed across the world to ensure business continuity

3 Syngene strengths

Syngene strengths

A global scale CRO/CDMO
- Integrated Drug Discovery, Development and Manufacturing service provider
- Small and large molecules, ADCs, oligonucleotides
- Listed on Indian Stock Exchanges (NSE and BSE)

Solutions through innovation
- IP fully assigned to clients
- Track record of data management and security
- Over 400+ patent filings by clients recognizing Syngene scientists

Quality matters
- Fully digitized quality organization
- Strong compliance track record with global regulators
- US FDA, EMA and PMDA approved, GLP certified, AAALAC accredited facilities
- 70 client and regulator audits in the last financial year

Science in our DNA
- Located in 3 top India life science hubs: Bangalore, Mangalore and Hyderabad
- ~5000+ qualified scientists including ~500 PhDs (~6,000 total headcount)
- Resilient supply chain management
- 2 Mn sq. ft. world-class R&D and manufacturing infrastructure. Large molecule capacity of 10,000 L and small molecule capacity of 70,000 L

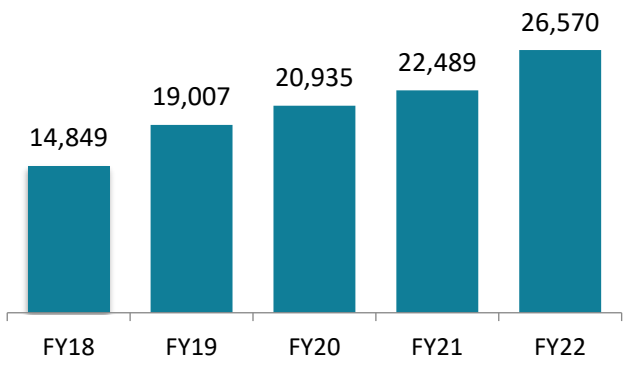
Blue chip client list
+ 400+ active clients
- Partnering with large / mid-size / emerging biopharma and other industries
- Clients concentrated in US, Europe & Japan
- Track record of working with diverse industry sectors

Making a difference
- Partnerships have delivered numerous clinical candidates
- Delivery history for integrated CMC programs up to clinical trials and beyond

Strong track record of growth and profitability

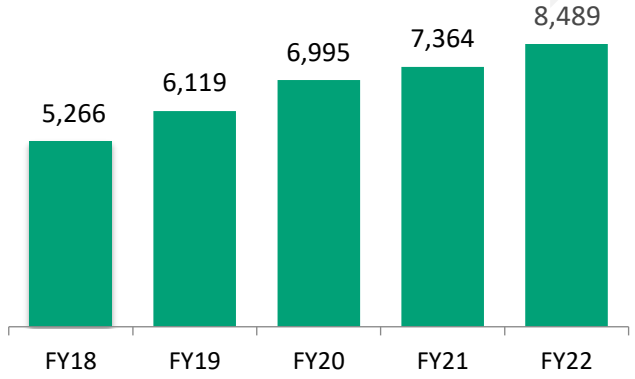
Total Revenue (Rs. Mn)

FY18 to FY22 - CAGR 16%



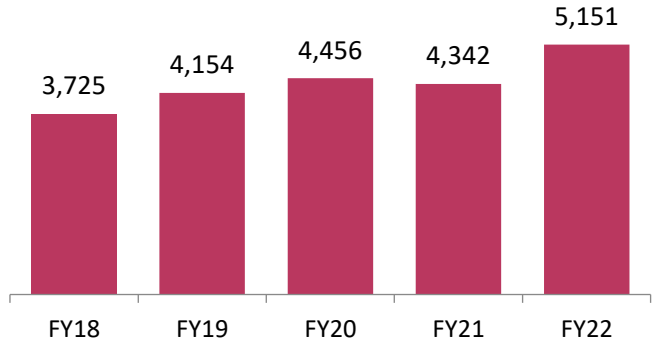
EBITDA (Rs. Mn)

FY18 to FY22 - CAGR 13%

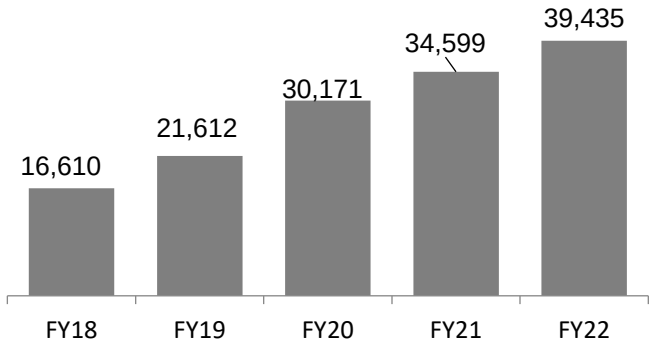


Profit Before Tax * (Rs. Mn)

FY18 to FY22 - CAGR 8%

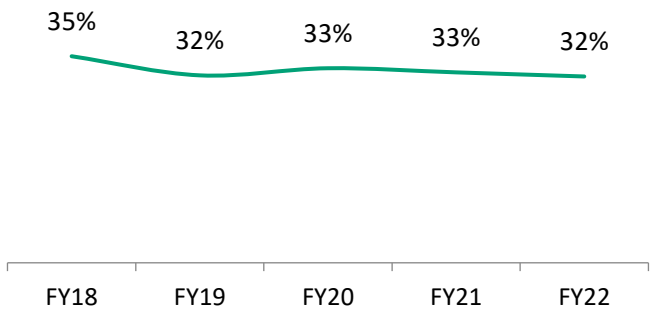


Gross Block^ (Rs Mn)



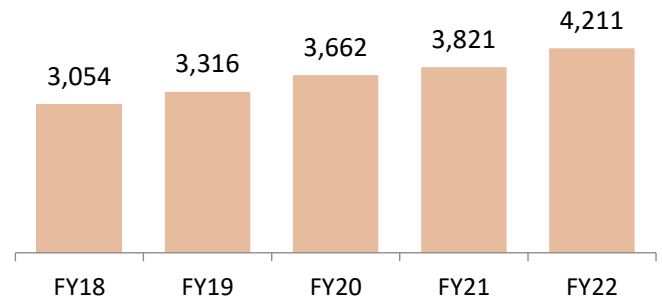
EBITDA margins

Sustained above 32%



Profit After Tax * (Rs. Mn)

FY18 to FY22 - CAGR 8%



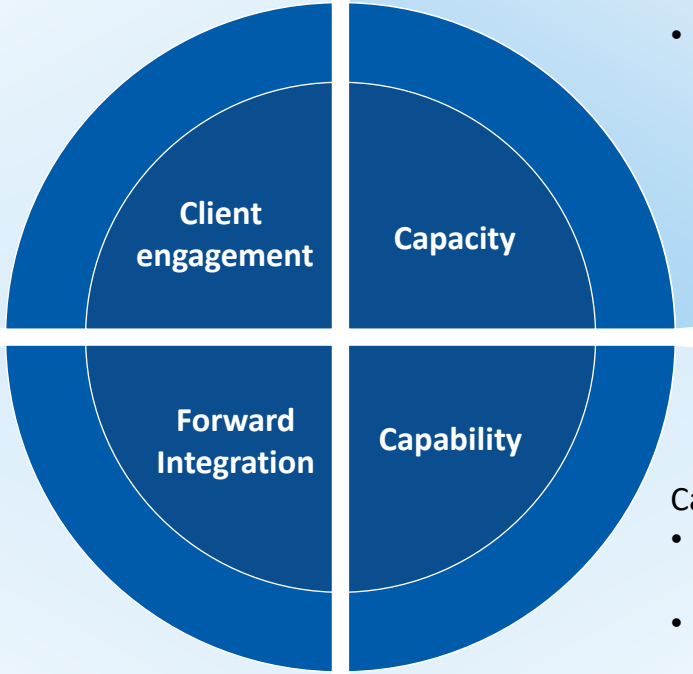
*Before exceptional items

^Tangible and Intangible Assets

Levers for future growth

Expand/extend existing clients
- Service integration
- Flexible business models including dedicated centers

Engage New Clients
- Tailored service offerings, high quality infrastructure and access to qualified personnel



Capacity expansion
- Continuous investment
- FTE services, manufacturing, formulation, biologics, stability

Offtake in commercial manufacturing in both biologics and small molecule API

Integrated Drug Discovery
- Proprietary model leveraging breadth of capabilities to deliver end-to-end project requirements

Capability additions
- New capabilities across multiple domains including adjacent sectors
- Stability, analytical and bio-analytical services, viral testing, clinical scale injectable fill finish
- New platforms: antibody drug conjugates, CAR-T, PROTACs

Committed to safety and sustainability

Safety is our first priority

- Accredited with ISO 45001:2018 for Occupational Health and Safety (OH&S) measures
- Risk assessments are an integral part of our operation: a proactive approach in incident prevention
- Kavach, our flagship safety program, has delivered improvement in safety metrics and drives focus on industrial safety for all employees
- 13.7 million manhours without Lost Time Incident (LTI) on rolling 12-month basis for FY22

Committed to environmental protection

- Accredited with ISO 14001:2015 for our Environment Management System
- **20%** reduction in freshwater usage; 152KL rainwater harvested
- **92%** of the total waste generated is recycled in an environment-friendly manner for FY22
- **3R's** operations constantly monitored to identify opportunities to reduce, reuse, and recycle waste
- **59,749 tCO2** emissions avoided in FY22
- **74 Mn KWH** of electricity usage from green energy sources - up 18% from FY21
- **85%** of total energy consumption from green energy sources in FY22

Refer to the CSR link on our website to know about our corporate social responsibility pursuits on healthcare, education, environment, rural development

All figures are as on March 31, 2022, unless otherwise specified

Industry recognition for our scientific capability and best practices

2018

- **Bio-Excellence Award 2018:** At Bengaluru Tech Summit, Bengaluru
- **Best Bioprocessing Excellence Award 2018** - At 5th Biologics Manufacturing Asia, Singapore
- **Healthcare Company of the Year 2018:** At the 7th Annual VC Circle Awards 2018, Mumbai
- **HR Excellence Award 2018 'For Best Talent Management Strategy':** World HRD Congress, Mumbai

2019

- Ranked as one of the **25 fastest growing companies in India** by Outlook Business
- **CMO Leadership Awards 2019** - Presented by Life Science Leader Magazine
- **FICCI CSR Award for Environmental Sustainability** -At the 17th Edition of the awards in New Delhi
- **Safe Workplace Champion Award** - At the 8th Manufacturing Supply Chain Summit and Awards
- **Best Leadership Development Program for Middle Management Award** - At the 6th Global Training and Development Leadership Awards
- **India Pharma Award 2019** - For "Excellence in Contract Research and Manufacturing Services" at CPhI & P-MEC India Expo.
- **Utthama Suraksha Puraskar 2019 -** (Pharma and Chemical Manufacturing Category) by National Safety Council of India (NSCI). Leadership Awards

2020

- **CMO Leadership Award Winner 2020 -** under Categories: Capabilities, Compatibility, Expertise and Service
- Bioprocessing Excellence Awards 2020 in the category 'Bioprocessing Excellence in South Asia—Viral Clearance and Safety Testing'
- **Great Place to Work Certified™ Company**
- (ASSOCHAM) CSR & NGO Awards 2020 for our contribution to COVID-19 relief work in Karnataka.

2021

- **Dream Companies to Work Award** at the 29th Edition of the World HRD Congress Awards.
- **Asian Leadership Award for Excellence in Branding and Marketing** in the Contract Research Development and Manufacturing category
- **CRISIL awards Syngene Top score among Indian Pharma:** for Environment Safety Governance (ESG)
- **Syngene ranked #69 in Fortune India magazine's** list of 'Top 100 Indian wealth creators 2021'
- **India Pharma Awards 2021** for Operational Excellence: Manufacturing organized by Informa Markets, India
- **Best Governed Company in the Listed Segment: Medium Category** at the 21st National Awards for Excellence in Corporate Governance by The Institute of Company Secretaries of India (ICSI)
- **Most Innovative New Learning Programme** at the L&D Vision & Innovation Award organized by Transformance Forums
- **Mahatma Award 2021** Under Health & Wellbeing Category
- **Best Corporate Foundation Award** at the World CSR Congress

2022

- **CMO Leadership Awards 2022** Received 6 awards for all categories, including Capabilities, Compatibility, Expertise, Quality, Reliability and Service
- **CMO Leadership Award Champion 2022** Additional Recognition received in CMO Leadership Awards 2022 for top performance in all **categories**
- **'Most Preferred Workplaces of 2022' by Team Marksmen Daily in association with India Today** Recognized for its holistic reorientation of the business landscape in the context of the pandemic, and for creating a collaborative and empowering culture for its employees.

Syngene

Robust risk management framework

Syngene has a risk management framework to identify, monitor, report and manage risk
Every risk owner monitors and manages risks relevant to their area of responsibility

Risk Owner

- Identify and mitigate risk in respective business areas

Executive Committee (EC)

- Sign-off on Enterprise Risk Framework annually
- Review and approve the key updates to enterprise risks and deep-dive into few risk areas every quarter

Board Risk Committee

- Sign-off on Enterprise Risk Framework annually
- Ensure that appropriate measures are in place to mitigate the risks
- Review updates to enterprise risks and deep dive into few risk areas every quarter

Board of Directors(BOD)

- Provide strategic direction on mitigation of risks
- Ensure principal risks are properly managed

Risk identification → **Risk assessment** → **Risk analysis and rating** → **Risk mitigation** → **Monitoring and reporting**

Refer Annual report for complete risk profile and risk mitigation strategy

4 Financials

Syngene

Q3FY23 financial highlights

Particulars	Q3 FY23	Q3 FY22	YoY Change	Q2 FY23	QoQ change
Revenue from Operations	**7,859**	**6,414**	**23%**	**7,681**	**2%**
Other income	172	129	34%	154	12%
Total Revenue	**8,031**	**6,543**	**23%**	**7,835**	**3%**
Material costs	2,061	1,721	20%	1,990	4%
Staff costs	2,192	1,954	12%	2,185	0%
Other direct costs	264	246	7%	288	-8%
Other Expenses	876	658	33%	868	1%
Foreign exchange (gain)/loss, net	156	-199	-178%	186	-16%
EBITDA	**2,482**	**2,163**	**15%**	**2,319**	**7%**
EBITDA Margin	***30.9%***	***33.1%***		***29.6%***	
Depreciation and Finance Costs	1,083	879	23%	1,019	6%
PBT	**1,399**	**1,284**	**9%**	**1,300**	**8%**
Tax	302	244	24%	280	8%
PAT before exceptional items	**1,097**	**1,040**	**5%**	**1,020**	**7%**
PAT Margin	***13.7%***	***15.9%***		***13.0%***	
PAT after exceptional items	**1,097**	**1,040**	**5%**	**1,020**	**7%**
PAT Margin (after exceptional items)	***13.7%***	***15.9%***		***13.0%***	

All figures in Rs. Mn unless otherwise specified

9MFY23 financial highlights

Particulars	9M FY23	9M FY22	YoY Change
Revenue from Operations	**21,985**	**18,461**	**19%**
Other income	481	381	26%
Total Revenue	**22,466**	**18,842**	**19%**
Material costs	5,664	5,342	6%
Staff costs	6,347	5,611	13%
Other direct costs	835	633	32%
Other Expenses	2,561	1,872	37%
Foreign exchange (gain)/loss, net	376	-457	-182%
EBITDA	**6,682**	**5,840**	**14%**
EBITDA Margin	***29.7%***	***31.0%***	
Depreciation and Finance Costs	3,057	2,479	23%
PBT	**3,627**	**3,360**	**8%**
Tax	771	627	23%
PAT before exceptional items	**2,856**	**2,733**	**5%**
PAT Margin	***12.7%***	***14.5%***	
PAT after exceptional items	**2,856**	**2,480**	**15%**
PAT Margin (after exceptional items)	***12.7%***	***13.2%***	

FY22 financial highlights

Particulars	FY22	FY21	YoY Change
Revenue from operations (excl export incentives)	**26,042**	**21,843**	**19%**
Other Income	528	646	(18%)
Total Revenue	**26,570**	**22,489**	18%
Material and power costs	8,138	5,839	39%
Employee costs	7,181	6,602	9%
Foreign exchange (gain)/loss, net	(548)	(171)	220%
Other Expenses	3,310	2,855	16%
EBITDA	**8,489**	**7,364**	15%
EBITDA Margin (%)	**32%**	**33%**	
Depreciation, Interest and tax	4,278	3,543	21%
Profit After Tax before exceptional item	**4,211**	**3,821**	10%
PAT Margin (%)	***16%***	***17%***	
Exceptional Items, net of taxes [3]	(253)	228	
Profit After Tax after exceptional item	**3,958**	**4,049**	(2%)

Balance Sheet Highlights

As on 31st March 2022

Shareholders' funds	32,976
Net Fixed assets	27,392
Other net assets [1]	(1,741)
Net cash/(debt) [2]	7,325
Total Use of Funds	32,976

(1) Other Assets calculated as (Inventories + Trade Receivables + Unbilled Revenues + Advance Tax + FX premium less (Trade payables + Others current liabilities) at the end of the year
(2) Net cash / (Net debt) calculated as the Cash & cash equivalents (Cash and bank balances + Current investments+ Fixed deposits) less Total debt (Short-term borrowings + Long-term borrowings) at the end of the year
(3) Exceptional item in FY22 is in relation to reversal of services export incentive related to FY20 in line with Government notification. In FY21 relates to receipt from insurance claim

Syngene

All figures in Rs. Mn unless otherwise specified

5 Shareholding and Share Information

Syngene

Syngene and Biocon Group

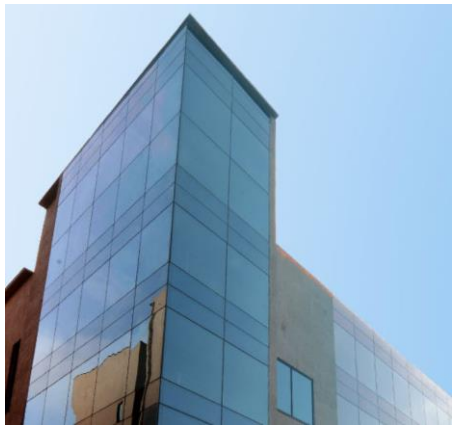
Syngene is an operationally independent publicly listed subsidiary of Biocon Limited, established in 1993 as India's first Contract Research Organization. Company has 25+ years of experience in novel molecule discovery, development and manufacturing services

Biocon Limited, founded in 1978, is an innovation-led global biopharmaceuticals company and has majority holding in key operating entities including Syngene

Syngene

Integrated services:

- Discovery research
- Development
- Manufacturing small/large molecules

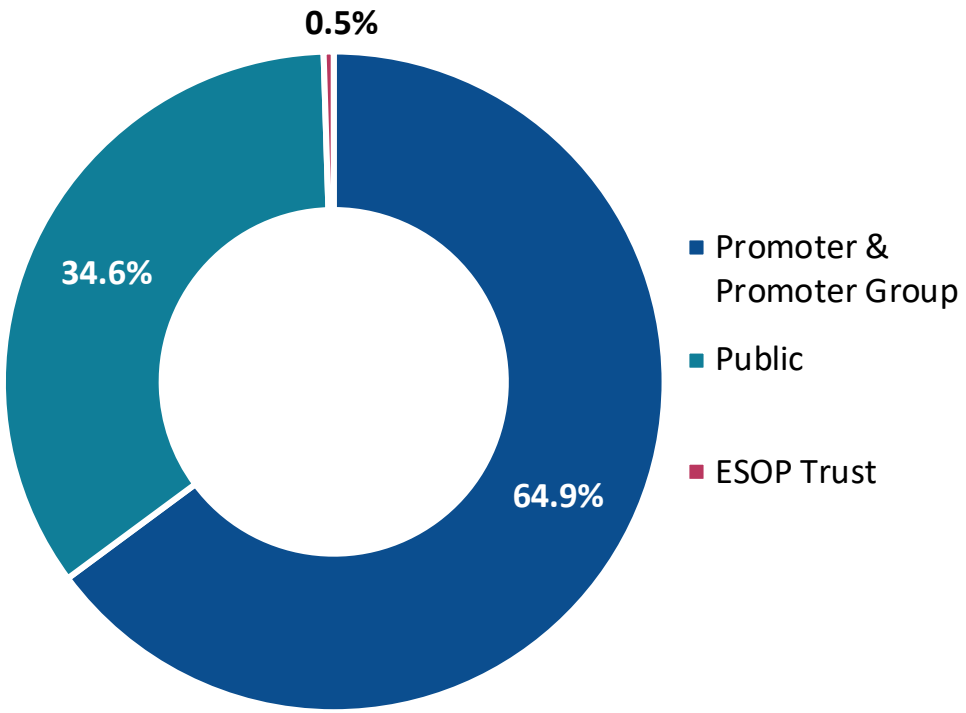


- Product Based
- Biosimilars
- Formulations and Compounds
- Alternative Therapeutic Drugs

Biocon *

Shareholding and Share Information

Syngene's Shareholding Pattern*



Syngene's Share Information*

NSE Ticker	SYNGENE
BSE Ticker	539268
Market Cap (Rs. Mn)	2,35,240
% free-float	35%
Free-float market cap (Rs. Mn)	78,031
Share Outstanding (Mn)	401

*As on 30th December2022

For more details

Visit our website www.syngeneintl.com

https://twitter.com/SyngeneIntl

https://www.linkedin.com/company/syngene-international-limited

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Appendix

Syngene

Discovery Services






	Target Identification and Validation	Hit Identification	Hit to Lead	Lead Optimization	IND Enabling	IND / Ph1 DE
Biology Translation	**Target ID** 1. Pathway analysis 2. Omics 3. Knock-in / knock-out **Hypotheses:** 1. Therapeutic 2. Mechanistic 3. Target Engagement	***In vitro* assays:** 1. Biochemical 2. Orthogonal 3. HTS Formats	***In vitro* assays:** 1. Cellular Mechanistic 2. Cellular Functional 3. Relevant Off-Target(s) ***In vitro* ADME assays:** 1. Protein Binding 2. Metabolism 3. CYP Inhib/Induct **Research Operating Plan:** 1. Assay Priority 2. Key Studies 3. Critical Path	***In vivo* assays/studies:** 1. PK (R/NR) 2. PD, PK/PD 3. Efficacy **Hypothesis:** 1. Patient Selection	**Later Translational:** 1. PK/PD/Efficacy 2. Refinement of patient selection hypothesis 3. Biomarkers **Human Dose Projection** 1. h-PK Projection 2. PK/PD/Efficacy data 3. Safety/Tox data	**Ph1-HV or Patient (as appropriate):** 1. Exposure 2. PD
Chemistry Development Formulation Clinical Development	**HTS/DEL/Fragments/Virtual Screening** 1. Library Design/Synthesis/ Maintenance 2. Hit validation, Resynthesis 3. Series Qualification, Prioritization		**Optimization:** 1. Biochem/Cell Potency 2. Selectivity 3. Phys/Chem Properties 4. In Vitro/Vivo Tool Cmpds	**Optimization:** 1. Tgt Optimal h-Profile 2. Candidate Selection 3. Backup Strategy	**Drug Substance (DS, aka API)** 1. Route Scouting (define specs) 2. Scale Up 3. Manufacture/Stability	**Drug Product (DP)** 1. Pre-Formulation Studies 2. Ph1 Suitable Formulation 3. Prototype/Stability 4. Manufacture/Stability 5. IND, BA/BE, DDI and Phase 1 clinical trials 6. GCP Bioanalysis
Safety Assessment			***In vitro* Safety:** 1. hERG 2. Ion Channels	**Tox-Suitable Formulation (maximize exposure)**	DRF Tox (R/NR) Bioanalysis GLP Tox (R/NR) GLP Bioanalysis	MTD or RP2D (as appropriate)

Informatics → **Iterative Data Analysis and Interpretation, Models, Hypothesis Generation**

Development Services and Manufacturing Services

	Developability Assessment	Development phase	Clinical Phase			Registration/process validation	Commercial batches
			Phase I	Phase II	Phase III		
Safety Assessment	Early PK, MTD/DRF studies, Exploratory Tox	• IND enabling GLP Tox studies: Ames, Chromosomal aberration, Micronucleus tests, Pivotal repeat dose (Rodent and Non- rodent) • Safety Pharmacology: CNS, Respiratory, CV Telemetry, hERG		• NDA enabling studies: Sub- chronic and Repro-tox studies • Local Tolerance study	Chronic and Carcinogenicity study		
Chemical Dev and Manuf.	• Route scouting • Process safety evaluation • Scalability	• Fit to purpose Process dev • Material supply • Impurity identification • Enable and scale • Tox material delivery	• Process dev , robustness and safety study • Unit operation studies • Impurity synthesis & characterization • DS clinical batch supply			• Process DOE, QBD and scale up studies • Process Risk assessment • FMEA analysis • Registration and process validation batches manuf.	Commercial batches manuf. and packaging
Formulation Dev and Manuf.	• Pre-formulation • Salt polymorph screening • Excipient compatibility	• Solid Oral & Injectable dosage forms • Enabling formulation technologies	Clinical Supplies for all phases • FIH formulation for Phase 1/2A • Final dosage form for Phase 2B/3 and onwards				
Analytical Services	Methods for Pre-formulation and Bio-analytical	• Methods for Intermediate, Final DS, DP • Forced degradation studies • Solid state characterisation	• Phase appropriate method validation for DS & DP (microbial methods) • Specifications for DS & DP • In process and Finished product analysis • Final batch release with COA • Reference standard , Impurities, Isolation and characterisation			Robustness of Analytical methods and full validation as per ICH	Analysis of commercial batches
Stability Services	Selection of suitable container closure system & packaging	• Development stability studies	• ICH stability for all phases • Shelf life Estimation • Re-test extension			Stability study of registration/ process validation batch	Stability study of commercial batches
Clinical Development			• Human Pharmacology Unit (Phase I/BE studies) • Clinical Trial Services – full solution provider for conducting trials in India • Central Lab Services including regulated bioanalytical lab • Clinical data management, biostatistics and medical writing				

Regulatory Support

Biologics Development and Manufacturing services





	Developability Assessment	Development phase	Clinical Phase			Registration/process validation	Commercial batches
			Phase I	Phase II	Phase III		
Process & analytical development	• Cell line development / selection • Process screening • Process characterization	• Clone to GMP • Upstream process Optimization • Viral clearance studies	• Process DOE, robustness and safety study • Unit operation studies • Impurity synthesis & characterization • DS clinical batch supply (non-GMP clinical & GMP) • CMC & regulatory support • Method development & testing			• Process risk assessment • FMEA analysis • Tech transfer package	• Commercial batches • manufacturing and packaging • technical support
Scale-up & QC/QA	• Methods for pre-formulation and bio-analytical	• Methods for intermediate, final DS, DP • Critical to quality parameter identification • Forced degradation studies	• Clinical phase process development & supply • Specifications for DS & DP • In process and finished product analysis • Viral clearance studies • Packaging and ICH storage stability and shelf-life estimation			• 3-Lot testing & equipment validation • Cleaning validation studies • Pre-audit preparation	• QC/QA analysis & release of commercial product w/ COA • Stability analysis • Root cause Investigation & CAPA management
Commercial production & supply chain	• Early screening of asset capability and capacity	• Capacity utilization planning	• Late phase clinical supply using manufacturing scale equipment • Supplier identification • Waste management plan • CAPEX requirement identification			• Supplier qualification • Pre-audit preparation • Protocol documentation • Master batch record development • Operation training	• Sales and operations planning • Delivery / logistics • Customer & regulatory audits • Process improvement & Regulatory filing updates

Regulatory Support

Syngene

Putting Science to Work

Thank you